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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,168	07/25/2005	Jens Lillegaard	P70187US0	6969

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JACOBSON HOLMAN PLLC
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WASHINGTON, DC 20004

EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,168	LILLEGAARD, JENS	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

With respect to applicant's arguments regarding the prior art of Cawood: Applicant argues that neither tube 29 or tube 37 are within the fluid retaining area. However, using applicant's own definition of the fluid-retaining area, both tube 29 and tube 37 are formed within the outer contours of the bag member, wherein the outer contours are defined by the joined edges joining the two outer film blanks. Applicant argues that tube 29 is formed on the outside of the bag and thus could not be within the fluid-retaining area. Applicant is referred to Fig. 2 of Cawood and Col. 3, lines 37-43 of Cawood, in which Cawood teaches that the inlet tube 29 communicates with valve 30 as can be seen by the dotted outlines of both tube 29 and valve 30, and further that the portion of tube 29 that does extend outside the fluid retaining area is a sleeve to receive catheter 13. It is the Office's position that the tube, while it has a portion that extends outside the fluid retaining area, is within the fluid-retaining area inasmuch as it is formed within the fluid retaining area, again according to the definition of the fluid-retaining area set forth in amended claim 1. Tube 37 is clearly within the fluid retaining area as it is so defined. This can clearly be seen in Fig. 2, where the outline of the bag, indicated generally at item 11 in Fig. 2, extends around the outer periphery of the tube 37 to include the tube 37 within the outer contour of said film blanks.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cawood (U.S. Patent No. 4,449,971).

With respect to **Claims 1,14**: Cawood teaches bag member 11 including at least two outer film blanks 11a,11b with joined edges 22-24. Bag 11 has inlet opening 29 heat sealed to blank 11a. Discharge portion 34 is positioned at a distance from inlet opening 29 in a lower portion of bag member 11 and includes pocket 37 (closure device) for storing tube 34 thus bringing the bag from a discharge position in which the bag is open, to a position of use in which the bag is closed and, wherein said discharge portion in the discharge position defines a longitudinal direction. Slit 38 (opening) serves as accommodating means within the outer contour of the bag for accommodating at least a part of said discharge portion 34. As can be seen in Fig. 2, slit 38 extends substantially transversely between tube 34 and tube 29. The bag member 11 includes at least a first and a second substantially tubular inner film elements, 29 and 37, wherein each said tubular film element is heat sealed to a film blank 11a or 11b by means of at least one joint as can be seen in Fig. 3. As is depicted in Fig. 2 and taught by Cawood, tube 37 is flexible and is positioned on a respective side of a longitudinal center dividing line parallel to that defined by said discharge portion 34. Tubes 29 and 37 each have a proximal and distal fold with respect to said dividing line. As can also be seen in Fig. 3, a joint between the first tubular film element 29 and film blank 11a and between the second tubular element 37 and blank 11b includes at least

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one proximal joint section (e.g. section nearest one way valve 30 for element 29) at or near the fold proximal the dividing line and at least one distal joint section distal with respect to said dividing line (e.g. section nearest heat seal 27 for element 29). Tube 29 is angled with respect to the dividing line, therefore the distance between at least a lower part of the proximal joint section and the proximal fold is smaller than the distance between at least a lower part of the distal joint section and the distal fold. These limitations are also satisfied by tube 37.

With respect to **Claims 2,15**: As stated previously, tube 29 is angled with respect to the dividing line, therefore the distance between at least a lower part of the proximal joint section and the proximal fold is smaller than the distance between at least a lower part of the distal joint section and the distal fold. These limitations are also satisfied by tube 37. Therefore the joint sections converge in the direction of the discharge portion.

With respect to **Claim 3**: As stated previously, the distance between at least a lower part of the proximal joint section and the proximal fold is smaller than the distance between at least a lower part of the distal joint section and the distal fold. The distance between the distal fold and the distal joint section (specifically the upper distal joint section) is smaller than the distance between the upper proximal joint section and the proximal fold.

With respect to **Claims 4,16**: Cawood teaches that the bag has a width of 20-40 cm and a height of 10-20 cm. AS can be seen in Fig. 2, the angle that tube 29 makes with the dividing line is substantially equal to the angle that the wall of one-way valve 30 makes with heat seal line 27 and also the angle that tube 37 makes with the dividing line, wherein the angle in degrees is in

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the range of \tan^{-1} (0.25) to \tan^{-1} (1), which is an angle between zero and 45 degrees, thus satisfying the limitation of claim 4.

With respect to **Claims 5,7,17**: Since the angle of inclinations of the tubular elements 29,37 are substantially identical, the distance between their respective lower ends of the proximal joint sections to the dividing line will be equal to one another, and since the discharge portion is centrally disposed about the dividing line, the sum of those identical respective distances will correspond to the cross-section dimension of the discharge portion 34.

With respect to **Claim 6**: As can be seen in Fig. 2, the proximal joint sections of the tubes 29,37 are substantially parallel to the proximal folds and the distance between the proximal fold and proximal joint section is smaller than the distance between the distal joint section and the distal fold.

With respect to **Claims 8,18**: An opening 38 is provided by a slit in the element 37, which provides a comfort layer (i.e. the layer facing outwardly from the user) and allows at least a portion of the discharge portion 34 to be lodged in the space between joint sections.

With respect to **Claims 9,19**: The film blanks 11 are laminated with an appropriate barrier material (reinforcing layer).

With respect to **Claim 10**: Both tubular elements are reinforced by heat sealed spots (reinforcing portion) at the joint sections to the respective film blanks 11.

With respect to **Claim 11**: One-way valve 30 (substantially tubular inner film element) is also provided in bag 11.

With respect to **Claim 12**: Tubular elements 29 and 37 are each provided in the area of the bag member 11 situated near the discharge portion. Examiner is considering the area near the discharge portion to be the portion of bag member 11 whose upper boundary is heat seal line 27 in Fig. 2.

With respect to **Claims 13,20**: As can be seen in Figs. 1,2, bag member 11 is substantially symmetrical with respect to said dividing line.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

March 27, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.